UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,736	03/22/2007	Toshiyuki Komori	0230-0232PUS1	3727

2292 7590 04/02/2010

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
FOX, DAVID T	
ART UNIT	PAPER NUMBER
1638	

NOTIFICATION DATE	DELIVERY MODE
04/02/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/560,736	KOMORI, TOSHIYUKI	
	Examiner	Art Unit	
	David T. Fox	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 March 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/15/05; 9/1/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *IDS 11/21/07; 1/30/08*.

Specification and Claim Objections

The specification is objected to for its omission of reference to the international application on page 1. The following paragraph should be inserted on page 1 of the specification, immediately below the title:

---This application is a 371 of PCT/JP04/08025 filed 09 June 2004.---

Claim 8 is objected to in its recitation in line 1 of "method for producing according to Claim 7" which is awkward and incomplete.

The following amendment would obviate this rejection. For brevity, the proposed amendment is set forth in the format for an Examiner's amendment, not for Applicant's amendment as set forth in 37 CFR 1.121(c).

In claim 8, line 1, insert ---the hybrid plant--- after "producing".

Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 7-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is indefinite in its recitation of "multiple fertility restorer genes" which fails to further limit claim 1, since claim 1 is drawn to the use of multiple copies of a single restorer gene. The following amendment would obviate this rejection.

In claim 3, line 1, insert ---copies of the--- after "multiple"; and in line 2, replace "genes" with ---gene---.

Claim 7 is indefinite in its recitation in line 3 of "a fertility restorer gene" as it is unclear whether this refers to any gene, or to the gene which has been inserted by genetic engineering. If the latter were intended, then replacement of "a" in line 3 with ---the--- would obviate this rejection.

Claim 8 is indefinite in its recitation in line 3 of "the fertility restorer genes" which fails to further limit claim 7, since claim 7 is drawn to the use of multiple copies of a single restorer gene. The following amendment would obviate this rejection.

In claim 8, line 3, insert ---multiple copies of the--- after "containing"; and replace "genes" with ---gene---.

Claim 9, line 1 is indefinite in its recitation of "the fertility restorer genes" which lacks antecedent basis in the claim. Deletion of "the" would obviate this rejection.

Claim 10, lines 2-3, is indefinite in the recitation of "a hetero individual of a single loci for the fertility restorer gene having only a single copy of the fertility restorer gene" which is awkward and unclear. The following amendment would obviate this rejection. See page 10 of the specification, lines 23-28, for basis for this amendment.

Replace the above phrase with ---an individual that has only one copy of the restorer gene at a single locus, and wherein the restorer gene is heterozygous at that locus---.

Anticipation

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by **Tang et al** (**1998**, Genetics 150: 383-391).

Claim 9 is broadly drawn to a restorer plant of any species, containing any fertility restorer genes homozygously at two or more loci.

Tang et al teach a sorghum restorer plant, line IS1112C, which is homozygous for two fertility restorer genes, namely *Rf3* and *Rf4*. See, e.g., page 384, column 2, second full paragraph; and page 385, Table 1, row 1.

Claim 9 is rejected under 35 U.S.C. 102(e) as being anticipated by **Brown et al** (**US 7,314,971** effectively filed 12 July 2002).

Brown et al teach *Brassica napus* plants containing two copies of the either the restorer Gene 16 or the restorer Gene 26, and plants produced by selfing these plants, wherein selfed plants would be homozygous for this gene at each locus (see, e.g., column 37, lines 26-39; column 38, lines 16-28 and 44-57).

Claims 1-2 and 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by **Mariani et al (US 6,046,382**).

Claims 1-2 are broadly drawn to a hybrid plant of any species, having two or more copies of any fertility restorer gene at two or more genetic loci which do not have a complete linkage relationship. The instant specification defines “not a complete linkage

relationship" as being at least about 1 centiMorgan apart (see, e.g., page 9 of the instant specification, lines 20-25). Claim 10 specifies that the hybrid plant has a higher seed fertility at low temperatures than a plant which has only one copy of the restorer gene, and which is heterozygous for the single copy of the restorer gene.

Claim 7 is drawn to a method for making the hybrid plant of any species, comprising introducing any fertility restorer gene by genetic engineering, and placing two or more copies of the restorer gene at genetic loci which are not completely linked. Claim 8 specifies that the fertility restorer gene in the restorer plant is homozygous at each locus, wherein the fertility restorer plant is then crossed to a sterile plant to produce the hybrid, wherein the genetic basis for sterility is unspecified.

Mariani et al teach the production of a fertility restorer plant by genetically engineering two copies of a barstar-encoding restorer gene into a *Brassica napus* plant, followed by selfing the plant to produce a plant which is homozygous for the restorer gene at each locus. Mariani et al also teach the crossing of this fertility restorer plant with a male sterile plant comprising a barnase-encoding sterility gene, to produce a hybrid plant.

See, e.g., Figure 1; column 1, lines 16-50; column 2, lines 20-45; column 5, line 55; column 13, lines 42-64; column 14, line 59 through column 15, line 53; column 16, lines 18-29 and 48-63; column 19, lines 42-60; column 20, lines 30-60.

Since claim 10 is not limited to a particular crop species, fertility gene or sterility gene; and since Mariani et al teach all the genetic limitations of the claimed hybrid plant,

it appears that the quality of enhanced seed fertility would have been an inherent property of the hybrid plant taught by Mariani et al.

See *In re Best*, 195 USPQ 430, 433 (CCPA 1977), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

See also *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

Obviousness

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 and 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Brown et al (US 7,314,971** effectively filed 12 July 2002).

Claim 3 is drawn to the hybrid plant of claim 1 wherein the copies of the restorer gene are located on different chromosomes. Claim 4 is drawn to the hybrid plant of claim 1 wherein the restorer gene is gametophytic.

Brown et al teach a *Brassica napus* plant which has been genetically engineered to comprise two copies of either the Gene 16 or the Gene 26 restorer genes, followed by selfing the plant to introduce homozygosity, as discussed above.

Brown et al also teach a method for crossing a restorer plant with a male sterile plant to produce hybrid seeds, and suggest the use of homozygosity for true-breeding reproduction of the restorer trait to progeny seed of the restorer plant. Brown et al also teach methods for isolating fertility restorer genes, and suggest that their method could be applied to any restorer gene in any crop species.

See, e.g., column 3, lines 1-17 and 50-65; column 7, lines 44-51; column 8, lines 55-59; column 12, lines 27-49; column 27, line 62 through column 28, line 15; column 34, lines 2-63; column 37, line 26 through column 38, line 29; column 38, lines 49-57.

Brown et al do not explicitly teach that the two copies of the restorer gene were on different chromosomes; that the restorer plants comprising two copies of a restorer gene were particularly chosen to produce hybrid plants; that the Gene 16 or Gene 26 are gametoyphytic; or that the hybrids comprising two copies of a restorer gene would have improved seed fertility at a low temperature.

It would have been obvious to one of ordinary skill in the art to utilize any of the restorer plants comprising genetically engineered restorer genes taught by Brown et al, including those restorer plants comprising multiple copies of the restorer gene due to *Agrobacterium*-mediated transformation, to produce hybrid plants via crossing with sterile plants; in the absence of evidence to the contrary.

It appears that choice of one or two copies of the restorer gene would have been the optimization of process parameters, in the absence of unexpected results. Moreover, it appears that enhanced seed set at low temperatures would have been an inherent property of the hybrid plants taught by Brown et al, in the absence of evidence

to the contrary, since they contain the same genetic components as the hybrid plant of claim 10; which is not limited to a particular plant species, a particular sterility cytoplasm, or a particular restorer gene.

One of ordinary skill in the art would recognize that some of the multiple-copy plants may have the restorer genes on two different chromosomes, given the random nature of *Agrobacterium*-mediated transformation. In the absence of unexpected results, the presence of unlinked multiple copies of the restorer gene on the same or different chromosomes would have been an obvious design choice.

It would have been further obvious to apply the techniques for isolating restorer genes, as taught by Brown et al, to a variety of plant species and restorer genes, as suggested by Brown et al, including gametophytic restorer genes, in the absence of unexpected results.

Claims 1-4 and 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hanson et al (US 7,164,058** effectively filed 10 January 2002) in view of **Mariani et al (1992**, Nature 357: 384-387), further in view of **Schoffl et al (1993**, Transgenic Research 2: 93-100).

Hanson et al ('058) teach a method for producing hybrid petunia plants, comprising the introduction of a fertility restoration gene by genetic engineering, wherein the restorer gene encodes a protein comprising a pentatricopeptide repeat (PPR) motif, followed by crossing the transgenic fertility restorer line with a male sterile line. **Hanson et al suggest** the use of an inducible promoter, including a heat-inducible promoter, to drive expression of the fertility restorer gene. **Hanson et al also suggest** the

advantages of homozygous fertility restorer genes, and suggest the use of at least two copies of the fertility restorer gene.

See, e.g., Figures 4 and 8; column 1, lines 25-39, 51-56 and 61-66; column 5, lines 44-65; column 6, lines 32-39; column 8, lines 26-29; column 9, lines 17-23; column 10, lines 14-15; column 13, line 42 through column 14, line 67; column 57, lines 1-17; column 58, lines 36-45; column 58, line 62 through column 59, line 7; column 62, lines 22-31; column 72, lines 36-43; column 75, lines 24-48; column 76, lines 1-30; column 78, lines 47-61.

Hanson et al ('058) do not teach a restorer plant with the same restorer gene at two different unlinked loci, including two different loci on different chromosomes.

Mariani et al (1992) teach that high levels of restorer gene expression may be needed for complete fertility restoration (see, e.g., paragraph bridging pages 385 and 386).

Schoffl et al teach that multiple copies of a transgene comprising a heat-inducible heat shock promoter, said promoter comprising a scaffold attachment region, resulted in higher levels of gene expression than single copies, wherein 4-5 copies gave the highest expression levels. **Schoffl et al suggest** that the use of scaffold attachment regions may result in higher levels of multiple-copy transgene expression in a variety of systems. See, e.g., page 93, Abstract, last sentence; page 95, Figure 2; page 97, Figure 3, and the first full paragraph of column 2; page 98, Figures 4A-B.

It would have been obvious to one of ordinary skill in the art to utilize the method of producing hybrid plants via crossing a male sterile plant with a fertile plant

homozygous for a genetically engineered fertility restorer gene, as taught by Hanson et al ('058); and to modify that method by incorporating higher levels of fertility restorer gene expression as taught by Mariani et al, utilizing multiple gene copy numbers and scaffold attachment regions as taught by Schoffl et al; given the suggestions by Hanson et al and Schoffl et al.

Choice of chromosomal location or type of restorer gene would have been the optimization of process parameters, in the absence of evidence to the contrary, as discussed above. Higher seed fertility under low temperatures would have been an inherent property of the resultant hybrid plants, as discussed above.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hanson et al (US 7,164,058** effectively filed 10 January 2002), in view of **Mohanty et al** (**1999**, Plant Science 147: 127-137, Applicant submitted), further in view of **Akagi et al** (**1994**, Current Genetics 25: 52-58).

Claims 5-6 are drawn to the above hybrid plant comprising two or more copies of a fertility restorer gene at two or more unlinked genetic loci, wherein the hybrid plant is rice and the fertility restorer gene is effective for BT sterility cytoplasm, including the restorer gene encoding an amino acid at least 70% identical to SEQ ID NO:49.

Hanson et al ('058) teach a method for producing hybrid plants comprising two or more copies of a fertility restorer gene, as discussed above. **Hanson et al ('058) also teach** the isolation of rice fertility restorer genes encoding proteins comprising PPR domains, including SEQ ID NO:22 encoding SEQ ID NO: 23; **and suggest** the use of rice as the crop to be transformed.

See, e.g., Figure 8; column 1, lines 61-67; column 2, lines 48-51; column 21, line 65 through column 23, line 65; columns 25-28; column 62, lines 5-11; column 62, line 60 through column 63, line 4; column 78, lines 9-23 and 38-61; column 79, line 8 through column 80, line 7.

SEQ ID NO:23 of Hanson et al ('058) is 86.8% identical to instant SEQ ID NO:49, **as evidenced by Hanson et al (2007b)**.

Hanson et al ('058) do not explicitly teach rice BT sterility cytoplasm.

Mohanty et al (1999) teach an *Agrobacterium*-mediated method of rice transformation, wherein up to 4 copies of the transgene were randomly introduced, without any ill effects on gene expression. **Mohanty et al suggest** the use of their technique to introduce a variety of useful transgenes into rice. See, e.g., page 128, column 1, second paragraph; paragraph bridging pages 128 and 129; page 132, column 2; page 133, column 1; page 135, paragraph bridging the columns.

Akagi et al (1994) teach that cytoplasmic male sterility in rice may be caused by the BT cytoplasm, wherein fertility is restored by the rice *Rf-1* gene, and wherein male sterility is useful for hybrid rice production. See, e.g., page 52; page 53, column 1, second paragraph.

It would have been obvious to one of ordinary skill in the art to utilize the method of making hybrids via crossing male sterile plants with male fertile plants comprising homozygous restorer genes as taught by Hanson et al ('058), and to modify that method by incorporating the rice fertility restorer gene also taught by Hanson et al;

by utilizing the rice transformation method of Mohanty et al and the BT cytoplasm taught by Akagi et al; as suggested by Hanson et al ('058) and Mohanty et al.

The transformation method of Mohanty et al would have introduced multiple copies of the restorer gene randomly throughout the genome, including different chromosomal locations, as recognized by the artisan of ordinary skill. SEQ ID NO:23 taught by Hanson et al ('058) would have been able to restore fertility to rice BT cytoplasm, since it is greater than 70% identical to instant SEQ ID NO:49. Choice of chromosomal location of incompletely linked genes would have been the optimization of process parameters, in the absence of evidence to the contrary. Increased seed fertility under low temperature conditions would have been an inherent property of the hybrid seeds taught by the combination of references, in the absence of evidence to the contrary.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hanson et al (US 7,164,058** effectively filed 10 January 2002), in view of **Mohanty et al** (**1999**, Plant Science 147: 127-137, Applicant submitted), further in view of **Kazama et al** (online publication **May 2003**, FEBS Letters 544: 99-102, Applicant submitted).

Hanson et al ('058) teach a method for producing hybrid plants comprising two or more copies of a fertility restorer gene, as discussed above. **Hanson et al also teach** the isolation of rice fertility restorer genes encoding proteins comprising PPR domains, **and suggest** the use of rice as the crop to be transformed, as discussed above.

Hanson et al do not teach the use of the BT sterility cytoplasm or a rice restorer gene which is 100% identical to instant SEQ ID NO:49.

Mohanty et al (1999) teach an *Agrobacterium*-mediated method of rice transformation, which randomly introduces up to 4 copies of the transgene without any adverse effects, and suggest the use of a variety of agronomic genes, as discussed above.

Kazama et al (May 2003) teach the isolation of the rice *Rf-1* gene, which gametophytically restores fertility to male sterile rice plants comprising the BT cytoplasm. The rice *Rf-1* restorer gene isolated by Kazama et al (May 2003) encodes a protein comprising PPR motifs. See, e.g., page 99, column 2, first full paragraph; paragraph bridging pages 99 and 100; page 100, column 2, penultimate paragraph; page 101, Figure 2; page 102.

The rice *Rf-1* restorer gene isolated by Kazama et al (May 2003) encodes a protein which is 100% identical to instant SEQ ID NO:49, **as evidenced by Kazama et al (2005).**

It would have been obvious to one of ordinary skill in the art to utilize the method of making hybrids via crossing male sterile plants with male fertile plants comprising homozygous restorer genes as taught by Hanson et al ('058), and to modify that method by incorporating the rice transformation method of Mohanty et al, and the BT cytoplasm and isolated rice *Rf-1* gene taught by Akagi et al; as suggested by Hanson et al ('058) and Mohanty et al.

The transformation method of Mohanty et al would have introduced multiple copies of the restorer gene randomly throughout the genome, including different chromosomal locations, as recognized by the artisan of ordinary skill. Choice of chromosomal location of incompletely linked genes would have been the optimization of process parameters, in the absence of evidence to the contrary. Increased seed fertility under low temperature conditions would have been an inherent property of the hybrid seeds taught by the combination of references, in the absence of evidence to the contrary.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hanson et al (2007a, SEQ ID NO: 35 from US Patent 7,164,058) teach a rice fertility restorer gene which encodes a protein having 63.4% identity with SEQ ID NO: 49.

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (571) 272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on 571-272-0975. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David T Fox/

Primary Examiner, Art Unit 1638

March 26, 2010